



**Karachi Bioethics Group
Institutional Ethical Guidelines for
Physician Pharmaceutical Industry
Interaction**

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Preamble



The pharmaceutical-physician relationship is drawing increasing attention all over the world in recent years due to the conflicts of interest inherent in interactions of physicians with the industry. There is a real, well demonstrated potential for physicians to lose their impartiality in prescribing drugs under the influence of their relationship with the industry.^{1,2,3,4,5,6} It is imperative that we guard against any and all threats against the objectivity of the medical decision making process and endeavor to maintain the professionalism and nobility expected from members of the medical profession. It must not be forgotten that the medical profession is regarded above all other professions as ‘a moral enterprise, based on a covenant of trust.’⁷

Unfortunately, the ethical core value of

medical practice is being seriously threatened due to the rampant commercialization that is rapidly turning medicine into a business enterprise. This has particular significance for developing countries like Pakistan where the absence of legal, ethical and moral frameworks, weak regulatory mechanisms and an expanding pay-for-service health system offers greater opportunities for exploitation of patients who are often illiterate and unaware of their rights.

The relationship between the pharmaceutical industry and the medical profession is coming under much scrutiny globally. There is growing disquiet among medical professionals and the public is demanding greater transparency in the interactions. In many countries there is a



move to redefine this relationship, through legislation and drawing up of new codes and guidelines. The Sunshine Act, 2008 in the USA is one such example.⁸

The Act provides for “transparency in the relationship between physicians and manufacturers of drugs, devices, biological, or medical supplies” and mandates reporting to the government “transfer of value to a physician” by the manufacturers.

The need for such an ethical framework in Pakistan has also been voiced for several years by concerned members of the medical community as well as by the general public. As things stand, there is little or no regulation of medical practice in Pakistan and physicians are at liberty to interact as they please with the industry.

Stories abound about the gifts being handed down to physicians by the industry, starting from insignificant trinkets such as pens and coffee cups, to favors such as air tickets for physicians and their families to resorts ostensibly for CME events, payment of monthly dues for leased cars and even refurbishing of private residences.^{9,10} What is alarming is that there appears to be no serious effort to curb such practices in Pakistan, and physicians have come to expect such perks as their right. This is in marked contrast to efforts being taken to stem these practices in the developed world.

We believe that if medical professionals in Pakistan are to regain public trust and re-establish their credibility, then it is



essential that their actions are grounded in ethics and morality, and their conduct is guided by a sense of personal integrity and professionalism. Moving towards ethical pharmaceutical-physician relationships constitutes a significant aspect of achieving this goal.

It is against this prevailing background in Pakistan that development of the PPI guidelines was undertaken by the KBG. The aim is to provide an ethical framework to guide the physician-pharmaceutical industry interactions in Pakistan in order to move from what *is* to what *ought to be*.



Process of Development of the Guidelines



The Karachi Bioethics Group (KBG) comprises individuals from different institutions in Karachi who share an interest in bioethics. The KBG was established in 2004 and since then is meeting every other month in one of the members' institutions each year, chosen on a rotational basis. (For a list of members and their institutions see Appendix 1.) In 2008, the KBG took upon itself the project of developing a set of guidelines for physician-pharmaceutical industry interactions. This was stimulated by rising concerns among physicians as well as the lay public about reports of unethical practices and increasing influence of drug and device companies on physicians.

Consequently, a working group was developed within the KBG which met on several

occasions to develop these guidelines. The working group went through several sets of guidelines already available (see Appendix 2), and took opinions from several physicians within and outside Karachi working at various institutions. Drafts were presented to the KBG over two meetings in which intense discussions took place before finalizing the guidelines. There was a variety of opinions within the group with some considering the guidelines as too idealistic to work within our environment. Some KBG members pointed out however that similar practices were already in place in their institutions and therefore are realistic and possible.

The document that follows represents the consensus of KBG members and was



reviewed in 2011. These guidelines primarily focus on physicians working in institutions and can serve as a resource for development of institutional guidelines.



Broad Principles



It should be the responsibility of health care organizations and academic institutions to cater to the educational, training and research requirements of their students, trainees, staff and faculty. One to one interactions between individual physician and pharmaceutical industry representatives for any purpose should be strongly discouraged to minimize the possibility of influence in the prescribing practices of the physicians. Any interaction between the medical fraternity and the industry required for the transfer of information regarding new products and innovations must be channeled through designated institutional processes.

These guidelines suggest the creation of a transparent process for conducting such activities for fund generation.

It is recommended that a common pool of money meant for CME and similar activities be created by the institutions and that funds from different sources including pharmaceuticals be kept in this pool. Institutions should develop transparent mechanisms to maintain and utilize funds from this common pool (see Appendix 3 for elaboration).



Disclosure



Definition: Disclosure is defined as the act of revealing (publicly) or uncovering.

Health care institutions should declare/disclose:

- Details of any support (cash or material) obtained by them from the pharmaceutical industry

Health care workers should declare:

- Details of their personal or their immediate families' financial involvements that may create a conflict of interest (see appendix 4 for definitions). These can include directorships/partnerships/shares in any pharmaceutical industry/medical supplies producer/retailer.
- This also includes ownership/partnership in hospital/clinic/pharmacy/chemist shop/optician shop/laboratory/radiology unit or any other similar business.

Suggested mechanisms for disclosure:

- Institutional Website
- Disclosure register accessible to physicians and staff



Gifts/Giveaways/Drug Samples



Accepting gifts of any kind and value from the pharmaceutical and device industry leading towards personal gain has the potential of influencing the physicians prescribing practices. This raises a situation of conflict of interest and should be avoided, We recommend that:

- One-to-one contact between physicians and the pharmaceutical industry representatives should be strongly discouraged.
- Physicians should not accept gifts of any kind and value from the pharmaceutical industry.
- The pharmaceutical industry should deposit all drug samples and giveaways with a designated institutional committee and not individual physicians. These can be then used to cater to the needs of poor patients.
- All medicines, equipment, books, travel support or any other money or material should be collected in a special pool overseen by a designated institutional committee. Members of the committee should command respect of all stakeholders as ethical individuals. Donors should have no influence over the utilization of funds from this common pool.



- Institutions must develop transparent mechanisms for disbursement of such funds making these known to all stakeholders.
- It is preferable that items such as books or equipment etc. donated by the industry should not display the name of a drug or product. The company logo and name can be displayed inconspicuously.



Scholarships and Educational Grants



Educational and other academic grants and support should ideally be provided by academic institutions. However, given the paucity of funds in academic institutions, reliance on pharmaceutical support cannot be entirely excluded. Scholarships, special grants and educational funds from pharmaceutical companies obtained by institutions for the trainees and faculty members should use the following guidelines:

- All funding should be directed to the institution and not individuals. It should be placed in a common pool established specifically for such donations/grants from the industry and meant for education. This common pool should be managed by a committee designated with the responsibility of handling such money.
- It should be for the institution, based on its policy for CME/educational activities, to decide how the money from this common pool is to be utilized without influence of the donor pharmaceutical companies.
- Recipients of grants should declare the utilization of such funds on the institutional website or in a publicly accessible register kept for such records.
- The physician working in an institution should not enter into contractual agreements with pharmaceutical companies



- If a physician is invited by a pharmaceutical company to present his/her own research data regarding one of their products, the physician may do so provided the following conditions are met:
 - The pharmaceutical industry has first approached the institution through its established process.
 - If funding for attending the event is involved, it is made available to the physician through the institution.
 - The physician should declare/disclose pharmaceutical industry support prior to his/her presentation.



Research



Ideally, all research funding should be provided by institutions. However, currently, support by pharmaceutical funding for research is a global reality. Research support from pharmaceutical industry should occur using the following guidelines:

- There should be no direct payments to the researcher / investigator by the industry for conducting research studies. All such research funding should be made to an appropriate institutional committee established for this function.
- Drugs, equipment or other consumable provided by the industry for research purposes should similarly be given to the relevant institutional committee designated for such work. Distinction must be made between drugs, equipment or consumable donated by a company to an institution as a philanthropic gesture and drugs provided for the purpose of research.
- Utilization of research funding should be at the institution's discretion. The funding industry must not influence the research agenda, methodology employed, participant selection, data analysis or publication of findings. All research proposals must be assessed and approved by the Ethical Review Committee (ERC) prior to initiation.
- Research involving human subjects and/or human materials, whether pharmaceutical funded or otherwise, should be approved by a properly constituted ERC which will be responsible for review of ethical issues including research agenda, informed consent, risks and benefits to participants and communities, etc.



- In case the institution does not have its own ERC, ethical review must be sought from an external ERC.
- Declaration of the funding by industry must be made by researchers in all publications and during presentations that emerge as a result of research.
- The institution involved should also declare the nature and amount of funding received for research on its website and other appropriate fora.



Pharmaceutical Industry Funding for CME Events



Large CME events including conferences, seminars, workshops etc should ideally be funded by academic institutions utilizing their own funds. Institutions can begin by relying on their own resources to hold events like guest lectures on a modest scale. Given the paucity of resources available to health care and academic institutions, they may have to turn towards the industry for support for larger events.

Pharmaceutical company organized drug information talks when arranged for updates should be held in hospitals and institutions and not in hotels, and should not include meals.

If industry support is required for organizing large educational events, it should be kept in mind that:

- All such support should come to the institution from a common pool created and maintained for this purpose and should not be directed towards individuals.
- Utilization of such funds should be at the discretion of an institutional committee responsible for organizing the event, without any influence of the funding agency.
- Pharmaceutical funding should not be sought for recreational or social events like a trip to the beach or a family day at an amusement park, etc.



- If a CME has a social event like a gala dinner or a musical evening, the event should not be held with donated funds and should be financed through sale of tickets to the audience.
- All industry support should be declared on the institutional website or using any other appropriate means.
- **Any advertising done by the funding industry at the time of a CME event needs to be :** done in a dignified and professional manner. There should be no advertising banners, hoardings, posters or any other material allowed within the academic/conference area. There should be a separate place designated for advertising activities so that the integrity of the academic arena is preserved.
- A declaration should be made by the pharmaceutical companies detailing their support for the CME event on their company website.
- The practice of flying in ‘foreign experts’ by the pharmaceutical companies should be discouraged. Since they are on a paid/supported tour, these experts can hardly be expected to present a non-biased, purely academic opinion in their talk due to the conflict of interest. Physicians should be encouraged to avoid such sponsored seminars and instead seek such drug information from relatively independent sources such as Cochrane Collaboration and other similar resources available on the internet.



Promotion of Products



Noting the unique status that physicians enjoy in society, it is recommended that they should not participate in product promotional activities like making appearances in advertisements, TV talk shows etc. meant to promote a product or brand. Institutions should consider developing a policy for their health care workers to check such occurrences.

If physicians are participating in public awareness programs on the media, the individual and institution should ensure that their appearance is governed by ethical principles and does not involve any financial or other personal gain introducing the element of conflict of interest. The primary focus of such non-promotional activities should only be the improvement in the health of the society.



Appendix



Appendix 1
List of KBG members
(At the time of developing the Guidelines)

1. Aamir Jafarey	Centre of Biomedical Ethics and Culture, SIUT
2. Aasim Ahmad	The Kidney Centre
3. Arshi Farooqui	Aga Khan University Hospital
4. Bushra Shirazi	Ziauddin University Hospital
5. Farhat Moazam	Centre of Biomedical Ethics and Culture, SIUT
6. Kausar S Khan	Aga Khan University Hospital
7. Khawar Mehdi	Pharm Evo
8. Maqbool Jafary	Karachi Institute of Heart Diseases
9. Mazhar Nizam	Patel Hospital
10. Moin Siddiqui	Ziauddin University Hospital
11. Mumtaz Lakhani	Ziauddin University Hospital
12. Murad Khan	Aga Khan University Hospital
13. Naila Rahman	Patel Hospital
14. Naima Zameer	National Institute of Child Health
15. Nausheen Saeed	Ziauddin University Hospital



List of KBG members

16. Nida Wahid Bashir	Patel Hospital
17. Rehana Kamal	Aga Khan University Hospital
18. Riff at Moazam Zaman	Aga Khan University Hospital
19. RubinaNaqvi	Sindh Institute of Urology and Transplantation
20. Salahuddin	Hamdard University Hospital
21. Samrina Hashmi	Pakistan Medical Association
22. Shahid Shamim	Dow University of Health Sciences
23. Shaukat Ali Jawaid	Pulse International
24. Shifa Naeem	Freelance Practitioner
25. Tayyaba Batool	National Institute of Child Health
26. Tufail Bawa	Patel Hospital
27. Yasmin Wajahat	Sobhraj Maternity Hospital



Appendix 2

Documents Consulted

- The WG-PPI would like to acknowledge the following documents/guidelines which were consulted in the process of compilation of the present guidelines.
- Code of Medical Ethics of the Pakistan Medical Association
- Guidelines for physicians in interactions with Industry. Canadian Medical Association Policy 2007.
- Guidelines for ethical relationship between physicians and industry. The Royal Australian College of Physicians. Third edition 2006
- Royal College issues new guidelines on gifts from drugs companies Ann McGuaran. London (<http://www.pubmedcentral.nih.gov/articlercndcr.fcgi?artid=1124049>)
- The relationship between physicians and the biomedical industries: advice of the Royal College of Physicians (http://www.rcplondon.ac.uk/news/statements/advice_biomedindustry.htm)



Appendix 3

Regulating Committee

Since KBG guidelines emphasize limiting interaction of health care workers with industry except through institutional routes, it is imperative that institutions devise transparent and acceptable mechanisms to do so. One such way is for institutions to constitute specifically mandated committees consisting of representation from all stakeholders including physicians, pharmacists and hospital administration in acceptable proportions. Institutions may even consider inclusion of lay members from outside the institution to enhance credibility.

In order for it to be viable, this committee should command the respect of all segments of the institution. It is this committee that should interact with the industry and be responsible for allocation of funds for CME or other relevant activities within the institution. Institutions should develop clear terms of reference for the working of this committee.

It is also recommended that institutions undertake educational efforts to enhance bioethical awareness among its staff and faculty.



Appendix 4

Definitions

Conflict of Interest: A situation that has the potential to undermine the impartiality of a person because of the possibility of a clash between the person's self-interest and professional or public interest.

Conflict of Interest in Medicine: Conflict of interest exists in medicine when the physician's primary responsibility to the patient is influenced by secondary competing considerations such as personal gain.



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